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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 719,053	12 07 2000	Robert Sullivan	13045-2US-1-	3285

20988 7590 07 30 2002

OGILVY RENAULT  
1981 MCGILL COLLEGE AVENUE  
SUITE 1600  
MONTREAL, QC H3A2Y3  
CANADA

EXAMINER

HUYNH, PHUONG N

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 07 30 2002

Please find below and or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/719,053

Applicant(s)

SULLIVAN ET AL

Examiner

" Neon" Phuong Huynh

Art Unit

1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE Three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 12/7/00; 5/29/02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) 1, 2 and 4 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice To Comply With Sequence Rules.

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### DETAILED ACTION

1. Claims 1-4 are pending.
2. Applicant's election with traverse of Group II, Claim 3 drawn to an immunocontraceptive vaccine which comprises administering an antigenic fragment of a p34 protein to elicit an immunocontraception response, filed 5/30/02, is acknowledged. The traversal is on the grounds that (1) Group I drawn to a method of immuno-contraception of male or female subject using the vaccine which comprises an antigenic fragment of a P 34 protein; (2) Groups I and II are closely connected together and (3) the search and examination of Claims 1 and 3 can be made without serious burden on the examiner. This is not found persuasive because of the reasons set forth in the restriction mailed 3/25/02. The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Berube *et al* (of record, biology Reproduction 51: 1255-63, 1994) teach a contraceptive vaccine for a male subject comprising administering to a male subject such as a hamster a composition comprising a hamster acrosomal sperm protein such as p26h to elicits an immune response to the protein such as antibody that blocks the binding of sperm to the egg (See page 1256, Inhibition of in vivo fertilization, in particular).

The claimed invention in claim 3 differs from the reference only the recitation of the antigenic fragment of a p34 protein, which is a human acrosomal sperm protein.

Berube *et al* (of record, Biology of Reproduction 51: 577-587, 1994) teach a human acrosomal sperm protein such as P34H that involves in acrosome reaction, sperm binding to the egg (See entire document). Boue *et al* further teach that antibody raised against the hamster acrosomal protein crossreacts with the human P34H on human spermatozoa, indicating that the antigenic binding fragment of two proteins are similar (See page 585, last paragraph, in particular).

Therefore, it would have been obvious to substitute the hamster acrosomal sperm protein as taught by Berube *et al* for the human acrosomal sperm protein such as P34H as taught by Boue *et al* for a contraceptive vaccine.

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have single general inventive concept and lack unity of invention.

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Further, a prior art search also requires a literature search. It is a burden to search more than one invention. Therefore, the requirement of Group II and Groups (I and III) is still deemed proper and is therefore made FINAL.

3. Claims 1-2 and 4 are withdrawn from further consideration by the examiner, 37 C.F.R. 1.142(b) as being drawn to non-elected inventions.
4. Claim 3 is being acted upon in this Office Action.
5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821 (a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 C.F.R. 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/or Amino Acid Sequence Disclosure.

This application fails to comply with the sequence rules because SEQ ID NO is required on page 7, line 31. Appropriate correction is required.

6. Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention.

The specification does not reasonably provide a **written description** of *any* immunocontraceptive vaccine for *any* antigenic fragment of *any* p34 protein in association with a suitable pharmaceutically acceptable carrier, wherein said vaccine elicits an immuncontraception response by said male or female subject after its administration for a contraception.

The specification discloses only antigenic fragments MELFLARGRVL (SEQ ID NO: 4) and CHKAKTMLNRI (SEQ ID NO: 5) for an immunocontraceptive vaccine.

With the exception of the specific fragments mentioned above, there is insufficient written description about the structure associated with function of *any* antigenic fragment of *any* P34 protein for an immunocontraceptive vaccine. Thus, Applicant was not in possession of the claimed genus. *See University of California v. Eli Lilly and Co.* 43 USPQ2d 1398.

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Applicant is directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

7. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

8. Claim 3 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 3 of prior U.S. Patent No. 5,989,549. **This is a double patenting rejection.**

(1) Claim 3 of the '549 patent recites an immunocontraceptive vaccine for a male or female subject, which comprises an antigenic fragment of a P34 protein in association with a suitable pharmaceutically acceptable carrier, wherein said vaccine elicits an immuno-contraception response by said male or female subject after its administration, which is verbatim of instant claim 3.

9. No claim is allowed.
10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to "Neon" Phuong Huynh whose telephone number is (703) 308-4844. The examiner can normally be reached Monday through Friday from 9:00 am to 6:00 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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11. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-7401.

Phuong N. Huynh, Ph.D.

Patent Examiner

Technology Center 1600

July 29, 2002

*Christina Chan*  
CHRISTINA CHAN  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600